



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,319	11/27/2000	Dale B. Schenk	15270J-004743US	6653
20350	7590	08/15/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			LYLES, JOHNALYN D	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/724,319

**Applicant(s)**

SCHENK, DALE B.

**Examiner**

Johnalyn Lyles

**Art Unit**

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 56-58, 61, 63-66, 68-69, 71-79, 81, 83, 85-86, 89, 92-94, 97, 99, 101-209 is/are pending in the application.
- 4a) Of the above claim(s) 83 and 101-163 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 56-58, 61, 63-66, 68, 69, 71-79, 81, 85, 86, 89, 92-94, 97, 99 and 164-209 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 56-58, 61, 63-66, 68-69, 71-79, 81, 83, 85-86, 89, 92-94, 97, 99, 101-209 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### **Status of Application, Amendments, and/or Claims**

1. The Examiner of U.S. Patent Application No. 09/724,319 has changed. In order to expedite the correlation of papers with the application, please direct all future correspondence to Examiner Lyles, Technology Center 1600, Art Unit 1649.
2. The amendment filed on 4/27/2005 under 37 CFR 1.312 has been entered.
3. Claims 83 and 101-163 have been withdrawn.
4. New claims 164-209 have been added.
5. Claims 1-55, 59, 60, 62, 67, 70, 80, 82, 84, 87, 88, 90, 91, 95, 96, 98 and 100 have been canceled.
6. Claims 56-58, 61, 63-66, 68-69, 71-79, 81, 83, 85-86, 89, 92-94, 97, 99, 101-209 are pending.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Rejections Withdrawn**

### ***Drawings***

Art Unit: 1649

The Examiner acknowledges Applicant's amendment to the Specification to include reference to Figures 15A-15E. Thus, the objection to the drawings for failing to comply with 37 CFR 1.84(p)(5) because 15A-15E are not included in the specification is **withdrawn**.

### ***Specification***

The examiner acknowledges Applicant deleted the embedded hyperlink and/or other form of browser-executable code. Thus, the objection of the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is **withdrawn**.

### ***Claim Rejections - 35 USC § 112, Second Paragraph-Withdrawn***

The rejection of claims **56**, **66**, and **97** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The rejection of claim **86** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

### ***Rejections Maintained or New, Necessitated by Amendment***

### ***Claim Objections***

Art Unit: 1649

Claim 195 is objected to because of the following informalities: Claim 195 recites, "the method of claim 195". Appropriate correction is required.

***Double Patenting Rejection-Maintained***

***Provisional Non-Statutory Double Patenting***

The Examiner notes Applicant proposes to hold the Double Patenting issues in abeyance until indication of allowability. Thus, the rejections are maintained until a terminal disclosure is filed.

Claims **56-58, 61, 63-66, 68-69, 71-79, 81, 85-86, 89, 92-94, 97, and 99** remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-30** of Application No. 09/580015 as noted in the previous Office Action (4/26/2004; pg 3-4).

**56-58, 61, 63-66, 68-69, 71-79, 81, 85-86, 89, 92-94, 97, and 99** remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-47, 135-135, and 144-145** of Application No. 09/979701 as noted in the previous Office Action (4/26/2004; pg 4-5).

New claims **183-209** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-30** of Application No. 09/580015 for the same reasons noted of record in the previous Office Action (4/26/2004; pg 3-4).

New claims **183-209** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-47,**

Art Unit: 1649

**135-135**, and **144-145** of Application No. 09/979701 for the same reasons noted of record in the previous Office Action (4/26/2004; pg 4-5).

***Claim Rejections - 35 USC § 112, 1st-Maintained***

Claims **57**, **58**, and **99** remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner notes that Applicant deposited the cell line producing the antibody 266 with the ATCC on July 20, 2004 and submitted as stated under MPEP §2406.02. Applicant amended the specification (pg 70, line 13) to recite the depository, accession number, and deposit date. Applicant amended claims **57**, **58**, and **99** to recite the ATCC accession number for the 266 antibody. However, there is no declaration the deposit was made under the Budapest Treaty or certification that the deposit meets the criteria as set forth below.

**If the deposit is made under the Budapest Treaty**, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific nucleic acid molecules have been deposited under the Budapest Treaty and that the 266 antibody will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. **If the deposit has not been made under the Budapest Treaty**, then in order to certify that the deposit meets the criteria

Art Unit: 1649

set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "*the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination.*" Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

***Claim Rejections - 35 USC § 112, 1<sup>st</sup>-Maintained and New,***

***Necessitated by Amendment***

Claims **56-58, 61, 63-66, 68-69, 71-79, 81, 85-86, 89, and 92-94** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Alzheimer's disease, does not reasonably provide enablement for "*therapeutically treating*" Alzheimer's disease in a patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

New claims **183-209** are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Alzheimer's disease, does not reasonably provide enablement for "*prophylactically treating*" Alzheimer's disease in a patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Examiner notes that Applicant amended claims **56-58, 61, 63-66, 68-69, 71-79, 81, 85-86, 89, and 92-94** to recite "*therapeutically treating*" Alzheimer's disease and to remove the broad recitation of methods for *treating and/or preventing amyloid-related diseases* by administering an antibody that binds to an amyloid deposit and added new claims 183-209 to recite prophylactically treating.

However, the specification is still insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of



Art Unit: 1649

working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims.

The specification does not enable "therapeutically treating." According to Stedman's Medical Dictionary therapeutic is define as follows:

Therapeutic: Relating to therapeutics or to the treatment, remediating, or curing of a disorder or disease. [G. therapeutikos]

Thus, "therapeutically treating" includes curing a disease, which is not enabled by the instant disclosure. In the instant case, the model system used in the instant Specification is not recognized as providing the teachings that are predictive of the results which would be expected for the full scope of the claims. As noted above, "therapeutically" is understood to mean "curing." Furthermore, "prophylactically" is known to mean "preventing," and based on the high level of required effect as defined in these terms, a high level of evidence showing "curing" or "preventing" is also required. The state of the art is such that there is currently no known cure for Alzheimer's disease (Ankarcrona and Winblad, Int Journal of Geriatric Psychiatry, 2005, 20:101-105; Souder and Beck Nurs Clin North Am., Sep 2004, 39(3):545-59), and those skilled in the art recognize that such technology is currently beyond scope.

Furthermore, as note in the previous Office Action (4/26/2004, pg 6), the specification teaches that the administration of particular anti-A $\beta$  antibodies is able to reduce  $\beta$ -amyloid levels within the brains of mice, which are transgenic for PDAPP and exhibit Alzheimer's type over production and build up of  $\beta$ -amyloid within the brain. Thus, while the specification demonstrates a level of protection using anti-A $\beta$  antibodies for passive immunization in the PDAPP mice, "curing" and "prevention" were not

Art Unit: 1649

achieved. The specification also discloses "patient" includes human and other mammalian subjects that receive either prophylactic or therapeutic treatment. The specification, as noted above, teaches reduced  $\beta$ -amyloid levels within the brains of mice. The specification is insufficient to enable one skilled in the art to practice the invention as broadly claimed. The specification fails to provide any guidance for successfully "therapeutically treating" or "prophylactically treating" human patients with Alzheimer's disease, and since resolution of the various complications in regards to treating Alzheimer's disease with an antibody is not complete, one of skill in the art would be unable to practice the invention without engaging in undue trial and error experimentation. The specification as filed does not provide any guidance or examples that would enable a skilled artisan to use the disclosed methods. Additionally, a person skilled in the art would recognize that predicting the efficacy of anti-A $\beta$  in humans in an Alzheimer's disease model as highly problematic (see MPEP §2164.03). Thus, although the specification prophetically considers and discloses general methodologies of using the claimed methods, such a disclosure would not be considered enabling since the state of the treatment of Alzheimer's diseases is highly unpredictable.

While the use of anti-A $\beta$  antibodies wherein said antibodies are specific for an epitope comprising residues 13-28 of A $\beta$  is feasible for treating Alzheimer's disease, Spooner *et al.* (13 December 2002, *Vaccine* 21(3-4): 290-297) teaches that the route of administration, the regiment of administration, and the genetic background of the mouse used affects the production of anti-A $\beta$  antibodies in response to A $\beta$  immunization (Table 1 and 2). It is also noted that although no deleterious effects were observed, this too

Art Unit: 1649

could be dependent upon genetic factors of the animal receiving the immunization (pp. 296). Thus, uncertainty is found by use of A $\beta$  as an immunogen in regards to possible autoimmune reactions, general deleterious side effects, and variability in the production of anti-A $\beta$  antibodies. Furthermore the Specification teaches that the 266 antibody binds to monomeric but not aggregated A $\beta$  (pp. 70 lines 19-20).

Walker *et al.* (July 1994, *Journal of Neuropathology and Experimental Neurology* 53(4): 377-383 (IDS#169) teaches the administration of a monoclonal anti- $\beta$ -amyloid antibody (10D5) into the cerebrospinal fluid of aged monkeys (pp. 377). Following injection, the monkeys were sacrificed and their brains examined to confirm that the antibodies injected labeled A $\beta$  plaques (Figures 1-5). It is noted that the monoclonal anti- $\beta$ -amyloid antibody (10D5) did not disaggregate, prevent, or inhibit A $\beta$  aggregation.

Also concerning passive immunization, Goldsby *et al.* (2002) *Kuby Immunology* 4<sup>th</sup> Ed. Chapter 18 "Vaccines" (pp. 449-465) teaches that passive immunization does not allow for the formation of immunological memory requiring continued dosages if the desired immunity is to be maintained. Also the issue of the antigenicity of the antibody administered must be taken into consideration because it can trigger an unwanted and possibly harmful immune response especially mouse antibodies administered to humans (pp. 451). Therefore, inadequate guidance is presented in the Specification to overcome these obstacles in practicing the invention to the full scope as claimed.

The specification of the instant application fails to provide adequate guidance for one of skill in the art to overcome the unpredictability and challenges of applying results from treatment and risk assessment of Alzheimer's disease in animals to humans as

Art Unit: 1649

exemplified in the references herein. Thus, for the aforementioned reasons therapeutic or prophylactic treatment of Alzheimer's disease in humans does not appear to be commensurate in scope with the claims {see Sipe (1992) *Annu. Rev. Biochem.* 61: 947-975}.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup>-New***

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c).

Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claims **56 and 183** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. In the present instance, claims 56 and 183 recite the broad recitation "prophylactically or therapeutically", and the claims also recite, "treating" which is the narrower statement of the range/limitation.

The scope of "prophylactically or therapeutically" and "treating" as defined by Stedman's Online Medical Dictionary are as follows:

Art Unit: 1649

Therapeutic: Relating to therapeutics or to the treatment, remediating, or curing of a disorder or disease. [G. therapeutikos]

Prophylactic: Preventing disease; relating to prophylaxis. Syn: preventive  
An agent that acts to prevent a disease. [G. prophylaktikos; see prophylaxis]

The scope of "treating" includes "caring for a patient" medically or surgically especially to improve or alter. The specification does not provide a standard for ascertaining the metes and bounds of the invention as claimed, and one of ordinary skill in the art would not be reasonably apprised of the scope of "therapeutically treating" or "prophylactically treating" as instantly claimed.

***Claim Rejections - 35 USC § 102-Maintained and New,***

***Necessitated by Amendment***

Claims **56-58, 61, 63-66, 68-69, 71-79, 81, 85-86, 89, 92-94, 97, 99, 164-209** are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 5,593,846 (14 January 1997) Schenk *et al.*

Dependent claims 77-79, 93-94, 164, 168-70, 188, 202, and 208-209 are rejected for depending from rejected base claims.

The claims recite a pharmaceutical composition of an antibody which specifically binds to an epitope within residues 13-28 of A $\beta$  and wherein said antibody is designated as "266". US 5,593,846 teaches an antibody, and antibody fragments (pg 9), including monoclonal and polyclonal and fragments (Fab, Fv, etc.), whose epitope lies within residues 13-28 of A $\beta$  and is known as 266, thus meeting the limitations of claims 97 and 99 (See Col. 4, lines 60-67; Col. 5, lines 1-5 and 28-35; Col. 13, lines 35-40; Col. 14, lines 13-28; and claim 7). The US Patent further discloses fragments and

Art Unit: 1649

"recombinantly produced antibodies (immunoglobulins) and variations thereof" (pg 8) that are well described in the patent and scientific literature including citing Harlow and Lane, *Antibodies: A Laboratory Manual*, (Cold Spring Harbor Laboratory), 1988. The reference teaches fusion to a bacterial protein (pg 17). The US patent is silent to chimeric or humanized as recited in the claims; however, reference to "recombinantly produced antibodies" includes chimeric antibodies (pg 8). Furthermore, according to the reference incorporated in the patent by Harlow and Lane (1988), methods of producing various antibodies including chimeric and humanized are disclosed. The reference contemplates pharmaceutical compositions incorporating a therapeutic or prophylactic amount of at least one compound and a pharmaceutically acceptable carrier. The pharmaceutically acceptable carrier can be any compatible, non-toxic substance suitable to deliver the compounds to an intended host, for example sterile water, alcohol, fats, waxes, and inert solids; pharmaceutically acceptable adjuvants, buffering agents, dispersing agents; and active agents (pg 11-12), which are all well described in the medical and scientific literature. Particularly, the reference teaches the antibody diluent consisted of Trizma base (see ELISA Assay protocol), and the antibody in phosphate-buffered saline (see antibody preparation). Thus, the reference meets the limitations of claims 165-169 and 172-182. The reference also contemplates the pharmaceutical compositions is suitable for systemic administration to the host, including both parenteral, topical, and oral administration and that the pharmaceutical compositions may be administered parenterally, i.e. subcutaneously, intramuscularly, or intravenously (pg 11-12). The recitation in the claims, "pharmaceutical composition" is

Art Unit: 1649

interpreted as an intended use and is not given patentable weight in this art rejection, and the composition of US 5,593,846 is not inconsistent with such a composition. Thus, the reference meets all the limitations in the claims.

***Claim Rejections - 35 USC § 102-New***

Claims **56-58, 61, 63-66, 68-69, 71-79, 81, 85-86, 89, 92-94, and 183-209** are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US 5,593,846 (14 January 1997) Schenk *et al.*

Dependent claims 77-79, 93-94, 164, 168-70, 188, 202, and 208-209 are rejected for depending from rejected base claims.

Schenk *et al.*, discloses administering the pharmaceutical compositions disclosed for prophylactic and/or therapeutic treatment of diseases related to the deposition of beta AP, such as Alzheimer's disease (pg 12). The reference also teaches the pharmaceutical composition comprising an antibody whose epitope lies within residues 13-28 of A $\beta$  and is known as 266, thus meeting the limitations of claims (Note rejection above regarding limitations of pharmaceutical composition and see Col. 4, lines 60-67; Col. 5, lines 1-5 and 28-35; Col. 13, lines 35-40; Col. 14, lines 13-28; and claim 7). The composition is administered to a host susceptible to the disease, but not already suffering from such disease identified by genetic screening and clinical analysis (pg 12). Thus, the reference meets the limitations in the claims to a method of administering a pharmaceutical composition for treating Alzheimer's disease.

**Claim Rejections - 35 USC § 103-New, Necessitated by Amendment**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **56-58, 61, 63-66, 68-69, 71-79, 81, 85-86, 89, 92-94, and 183-209** are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,593,846 (14 January 1997) Schenk *et al.*, further in view of US 5,530,101 (25 June 1996) Queen *et al.*

Dependent claims 77-79, 93-94, 164, 168-70, 188, 202, and 208-209 are rejected for depending from rejected base claims.

US Patent 5,593,846 teaches an antibody whose epitope lies within residues 13-28 of A $\beta$  and is known as 266, thus meeting the limitations of claims 97 and 99 (See Col. 4, lines 60-67; Col. 5, lines 1-5 and 28-35; Col. 13, lines 35-40; Col. 14, lines 13-28; and claim 7).



The reference, US 5,593,846 does not recite a "chimeric or humanized" antibody. However, it would have been obvious to the person of ordinary skill in the art at the same time the invention was made to modify the teachings of Schenk *et al.* and to produce humanized or chimeric antibodies. Chimeric antibodies are somewhat successful in overcoming the limitations of monoclonal antibodies and humanized antibodies are important because they bind to the same antigen as the original antibodies, but are less immunogenic when injected into humans (US 5,530,101, see Background of the Invention, pg 1-2). The person of ordinary skill in the art would have been motivated to make the modifications because humanized and chimeric antibodies, which have the same or similar binding specificity and affinity as the nonhuman antibody that provides the starting material for its construction are useful in treating diseases in humans whereas antibodies, such as monoclonal antibodies are often immunogenic when injected into humans. The person of ordinary skill in the art would have reasonably expected success because methods of producing chimeric or humanized antibodies are well described in the art.

### ***Conclusion***

No claims are allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnalyn Lyles whose telephone number is 571-272-3433. The examiner can normally be reached on M-F 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jdl

  
**JANET L. ANDRES**  
**SUPERVISORY PATENT EXAMINER**